

Exhibit 5



U.S. Department of Justice

Civil Division, Fraud Section

601 D Street, NW
Ninth Floor
Washington, D.C. 20004

Telephone: (202) 305-9300
Telecopier: (202) 616-3085

Via Electronic Mail

May 2, 2011

Paul Carberry
White & Case LLP
1155 Avenue of the Americas
New York, New York 10036-2787

Re: In re: Pharmaceutical Industry Average Wholesale Price Litigation,
MDL No. 1456/Civil Action No. 08-10852-PBS (D. Mass.)

Dear Mr. Carberry:

Thank you for your letter of April 28, 2011 which responded to the Government's request that you withdraw the Notice of Subpoena and Rule 30(b)(6) specifications that you recently posted on LexisNexis. I will address the points you raised in the order set out in your letter.

Touhy Regulations

You note that the Touhy regulations apply to the testimony of agency employees and that the subpoena by defendants was directed to CMS as an "entity." It is difficult to understand the point you are trying to make here. Are you suggesting that CMS can somehow respond to the deposition specifications you posted other than through the testimony of a current or former employee of the agency? That question aside, the case cited in your letter, *Orange Environment, Inc. v. County of Orange*, 145 F.R.D. 320 (S.D.N.Y., 1992), which you contend supports the idea that the Touhy regulations do not apply to depositions of an entity, does not contain any such holding. Indeed, the court in that case, in *dicta*, describes how a litigant might resolve disputes with the agency, noting that if the agency declined to offer any testimony in response to Rule 30(b) (6) specifications, the requesting party could file suit against the official rendering its decision, claiming that such refusal was "arbitrary, capricious, or an abuse of discretion." *Id.* at 324. This is essentially the same standard that would apply in the context of a Touhy request. Moreover, requests to CMS in the manner prescribed by the agency's Touhy regulations are how defendants in the AWP-MDL have attempted to obtain testimony from CMS on particular issues until now. (Except to the extent, as described below, that MDL parties were permitted to question agency personnel who appeared in response to a Rule 30 notice served by one of defendants against which the United States intervened.) The recent subpoenas served by you and counsel for Actavis are, as far as I know, the first to depart from this process.

Finally, you have suggested that you proceed with the existing Rule 45 subpoena and pursue a Touhy request simultaneously. This suggestion seems unworkable as well as legally

doubtful. In short, you need to make an election as to which procedure you will use – notwithstanding that either one would be both untimely and overly burdensome. It bears emphasizing that, for the reasons discussed below, any attempt to take deposition discovery pursuant to the Touhy regulations would also be improper in light of existing orders in these cases. Withdrawal of the Notice in favor of compliance with the Touhy process would put the dispute in the correct procedural posture - but not resolve it.

Timeliness of the Subpoena

My previous letter cited the items in the record which suggest that the Court, via a few lines in a March 28 docket entry, was not reopening discovery with the expectation that the parties would serve wholly new discovery and extensive requests. For example, the Court did not establish new dates for the ensuing expert discovery, which began almost simultaneously with the close of fact discovery. Although you dispute this point, your letter does not identify any clear indication by the Court to support the contention that Judge Saris intended to allow the parties to engage in extensive new fact discovery.

Earlier in the AWP-MDL, the United States advised other litigants that at least one judge in the District of Massachusetts had held that conducting depositions outside the discovery period – even with the agreement of all counsel – would constitute a violation of the operative CMO. *Accord* Local Rule 16.1(G) ("The scheduling order . . . can be modified only by order of the judge . . ."). Notably, the United States took this position in the MDL with respect to depositions of *defendants'* employees which the Government had noticed *prior to the discovery deadline*, but which had not gone forward based on the availability of the witnesses. In short, we declined to mutually agree with defendants to schedule any depositions, including those already noticed by the United States, until the Court explicitly ordered an extension of the discovery cut-off. We believe the same constraint applies here.

In the present situation, we cannot accede to your request that we be cavalier as to the issue of whether discovery closed by virtue of CMO No. 32 – which is the only record entered by the Court that expressly and unambiguously addresses the issue. As the parties propounding new discovery, it is up to defendants to resolve this issue with the Court before moving forward with the depositions.

Burden of Compliance

In my last letter, I noted that you had already had the opportunity to question CMS officials who are knowledgeable about approval of state plan amendments during earlier depositions in the AWP-MDL. Notably, you have not contested this point. Instead, you raised a different issue by asking me to identify existing testimony on the particular subjects listed in your recently-posted specifications. The point here does not pertain to the level of detail covered in the earlier depositions, but rather concerns the opportunities that Sandoz counsel – indeed any party – had to question CMS officials at deposition on whatever subjects they liked. As made very clear throughout the Government's involvement in the AWP-MDL, the Judicial Panel's transfer of the False Claims Act cases to the AWP-MDL was for the purpose of efficient and

consolidated discovery – for the benefit and convenience of *all concerned*. Consistent with that transfer and consolidation, during the litigation with Abbott, Dey and Roxane, the Government consistently allowed questioning by other parties in the AWP-MDL. For example, DHHS employee David Tawes was questioned by ten different lawyers over the course of four deposition days. Although we extensively litigated certain discovery issues with Abbott, Dey and Roxane (mostly relating to privilege), there was never a single complaint, by any MDL litigant, concerning the level of access allowed by the Government to agency witnesses over the multiple years that discovery was open in the Government’s cases.

By my rough count, White & Case attorneys attended at least 39 depositions of present or former DHHS personnel. From the record, it appears that those lawyers generally passed on their repeated opportunities to question Government witnesses, even though they were in attendance for hundreds of hours of depositions and must have noticed that other MDL defendants were using the opportunity. We believe the Court will question the burdensomeness and need for the subpoena in light of the abundant access given to MDL parties by the Government to its personnel.

Finally, the specifications are over broad, burdensome and appear to be an attempt to obtain privileged information. For example, specification one, which covers drug pricing information, including AMPs, provided to CMS by defendants for their products, without any limitation, appears not only vastly over broad but pointless. Defendants presumably already know what pricing information they provided to CMS in connection with the Medicaid Rebate Program. With respect to CMS’s “consideration” of proposed amendments to State Plans, the agency’s deliberations on whether to approve an amendment is subject to the deliberative process privilege. Accordingly, there is no point in the agency designating a witness who would be constrained by privilege from addressing a principle area of inquiry in the specifications you posted.

Lack of Compliance with CMO Service and Scheduling Provisions

You have also asked for additional detail concerning defects with service of the subpoena. As you would expect, these defects are of less significance to the Government than the issues noted above. However, given we would likely cover this ground in any filing with the Court, I will note a few salient points. With respect to third-parties, the operative CMO specifies that a deposition is initiated by service of a subpoena pursuant to Rule 45, thereafter there should be conferral between counsel regarding the date and location of the deposition, and, as a third and final step, the party serving the subpoena is supposed to post the subpoena on LexisNexis File & Serve. See CMO No. 32 §14(L). You completely failed to follow steps one or two, and jumped straight to step three. As indicated above, per CMS’s regulations, you should have initiated this effort by serving a Touhy request on CMS. Even if you dispute this, which is unclear from your letter, service of the subpoena should have been pursuant to the particular service provisions set out in Rule 45(b). In any event, regardless of how you intended to effect service, the next step should have been conferral with counsel. Instead, you went straight to step three and simply posted the notice with LexisNexis.

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Local Rule 37.1

You have stated that issues regarding the subpoena warrant further discussion, but you have not identified them or proposed any agenda for a teleconference. In light of the substantial problems associated with the Notice which you posted and the very considerable burden that CMS shouldered over the course of the MDL, I do not see a middle ground on which we could resolve the Government's objections. My primary concern now is with the preparation and timely filing of a motion to quash. Paragraph 14(K) in the CMO specifies that protective order motions should be filed within 20 days of the letter containing the initial request. It is uncertain whether this provision applies with respect to your recent Notice given the lack of an initial request and the fact that the United States is not a signatory to CMO No. 32. In any event, in order to obtain reasonably prompt judicial resolution of this matter, we anticipate that the Government will file a motion to quash on or before May 6, 2011. Based on your last correspondence, we will advise the Court that attempts to resolve the dispute were unsuccessful.

In conclusion, in light of, *inter alia*: the lack of a court order clearly extending the deadline for new discovery in this case; the plain language of the Touhy regulations; the previous Touhy compliance by other MDL defendants; the Touhy request you now have pending with the agency; the failure to take advantage of deposition opportunities during the AWP-MDL; and the non-compliance with scheduling procedures in the CMO, CMS will not be producing a witness for deposition on May 6, 2011. In view of the burden associated with preparing a motion to quash, please reconsider whether you will withdraw the Notice and subpoena. Please feel free to contact me at Justin.Draycott@USDOJ.gov. Thank you for your attention.

Very truly yours,

/s
Justin Draycott
Trial Attorney
Commercial Litigation Branch